Supplementary Table 3. Adverse drug reactions (by system organ class)

Variable	Safety analysis set (*n*=3,231)
Total number of AE	606
Patients with an AE	450 (13.93)
Total number of ADR	193
Patients with an ADR	166 (5.14)
Type of ADR[a]	
Gastrointestinal disorders	22 (0.68)
Infections and infestations	17 (0.53)
Nervous system disorders	14 (0.43)
General disorders and administration site conditions	10 (0.31)
Investigations	21 (0.65)[b]
Weight decreased	17 (0.53)
Renal and urinary disorders	28 (0.87)
Pollakiuria	19 (0.59)
Reproductive system and breast disorders	32 (0.99)
Vulvovaginal pruritus	18 (0.56)
Pruritus genital	9 (0.28)
Metabolism and nutrition disorders	8 (0.25)
Hypoglycemia	3 (0.09)
Skin and subcutaneous tissue disorders	19 (0.59)
Pruritus	15 (0.46)
Musculoskeletal and connective tissue disorders	4 (0.12)
Respiratory, thoracic, and mediastinal disorders	3 (0.09)
Injury, poisoning, and procedural complications	3 (0.09)
Vascular disorders	1 (0.03)
Psychiatric disorders	1 (0.03)
Ear and labyrinth disorders	2 (0.06)
Blood and lymphatic system disorders	2 (0.06)

Values are presented as number (%).
AE, adverse event; ADR, adverse drug reaction.
[a]Classified by system organ class (MedDRA version 20.0), [b]Composed of 17 subjects with weight decrease, 1 subject with weight increase, 1 subject with abnormal electrocardiogram, 1 subject with hemoglobin decreased, and 1 subject with urine output increased.